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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,375	10/09/2001	Donald Gerald Stein	07157/239838 (5543-17)	5877

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/973,375	STEIN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's response filed on August 23, 2002 in Paper No. 7. Currently, claims 1-20 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roof et al. (43, 44, and 45, PTO-1449 submitted April 8, 2002) and Gee et al. (Re. 35,517, PTO-1449 submitted April 8, 2002) in view of Applicant's admission regarding the prior art in the specification (see page 2) for reasons of record stated in the Office Action dated April 23, 2002.

Applicant's remarks filed on August 23, 2002 in Paper No. 7 with respect to this rejection of claims 1-20 made under 35 U.S.C. 103(a) of record stated in the previous Office Action April 23, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

First, Applicants arguments regarding the Examiner's position that "applicant's admission regarding the prior art also teaches that a traumatic brain injury to CNS is

tightly associated with GABA" are not found persuasive since Applicant's admission regarding the prior art in the specification at page 2 lines 28-31 clearly teaches that "[f]ollowing a traumatic injury to the central nervous system, a cascade of physiological events leads to neuronal loss including, for example, an inflammatory immune response and excitotoxicity resulting from the initial impact disrupting .... $GABA_A$.. receptor system". Thus, Applicant's admission regarding the prior art in the specification clearly teaches that a traumatic brain injury to the central nervous system is tightly associated with GABA, and supports the Examiner's position.

Moreover, Applicants are requested to note that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim nonobvious as set forth in the 103 rejection in the previous Office Action. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Further, Applicants' assertion that a *prima facie* case of obviousness requires the prior art to suggest the claimed invention without references to the Applicants specification, is not found persuasive. Applicants are also requested to note that what the Examiner cited in the rejection is the prior art as Applicant's admission in the specification – "Background of the Invention".

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning --"the Examiner has merely used Applicants' claims as a guide and selected references at random that mention various aspects of the claimed invention" and using hindsight reconstruction of the claimed invention, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 170 USPQ 209 (CCPA 1971). See MPEP 2145. As discussed in the previous Office Action, progesterone is known to be useful in a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to the central nervous system (CNS) according to the cited prior art. Allopregnanolone, is a well known to be a particular progesterone metabolite, having the same therapeutic usefulness as progesterone in CNS, e.g., neuroprotective properties modulating GABA receptor and increasing the effects of GABA, which is further supported by the disclosure in Gee et al. Therefore, one of ordinary skill in the art would have expected that the particular progesterone metabolite, allopregnanolone, would be useful in the claimed methods herein for treating a tramatic central system injury and decreasing neurodegeneration in a subject following a traumatic injury to CNS, as progesterone, with a reasonable success, absent evidence to the contrary.

Therefore, motivation to combine the teachings of the prior art to make the present invention is seen and no impermissible hindsight is seen. The claimed invention is clearly obvious in view of the prior art.

Applicant's results shown in the Examples 1-7 of the specification at pages 20-40 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below.

It is noted that progesterone is employed in the testing of Example 6-7. Thus, Applicant clearly acknowledges that progesterone and its particular progesterone metabolite, allopregnanolone, have the same therapeutic usefulness as discussed by the examiner above. Therefore, Applicants' experiments further supports the examiner's position for the motivation for the employment of allopregnanolone in the instant invention.

Secondly, the results in Examples 1-5 on the employment of the particular progesterone metabolite, allopregnanolone, show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c).

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
November 5, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

11/16/02